

REMARKS

After amendment, claims 1-3 are pending in the present application, claims 4-12 having been cancelled without prejudice pursuant to the Examiner's restriction requirement and Applicants' election to prosecute the group I invention and a carbomer species having an allyl ether linking moiety which is hydrolytically susceptible. The present invention relates to polyanionic polymers which are linked through hydrolytically susceptible groups to afford polyanionic polymer segments of relatively small molecular weight which may be passed out of the body because of their limited size, which is an important aspect of the present invention. The polymers according to the present invention are susceptible to hydrolysis and used in conformity with those physicochemical characteristics.

The Examiner has objected to the disclosure and rejected claims 1-3 variously under 35 U.S.C. §112, second paragraph, §102 and/or 103 for the reasons which are set forth in the office action on pages 3-6 of the office action. Applicants respectfully traverse the Examiner's rejections of the instant application.

The Objection to the Specification

The Examiner has objected to the specification for the reasons which are stated on page 3 of the office action. Applicants have amended page 8, page 25, line 27 and page 33, line 17 to address the Examiner's objections. It is now respectfully submitted that the specification is in compliance with statutory requirement and the Examiner is respectfully requested to withdraw the objection to the specification.

The §112, Second Paragraph Rejection

The Examiner has rejected claims 1-3 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention for the reasons which are stated in the office action on page 4. Essentially, the Examiner rejects the claims based upon the use of the term "molecular weight" in claims 1 and 2 and "average molecular weight" in claim 3 as being ambiguous absent further definition. Applicants respectfully traverse the Examiner's rejection.

Applicants have used the term “molecular weight” in claims 1 and 2 according to its typical meaning used by polymer chemists. The molecular weight in claims 1 and 2 refers to the total or absolute molecular weight in kilodaltons of the polyanionic polymer segments which make up the polymer. Claim 1 indicates that 90% or more of the polyanionic polymer segments have an actual molecular weight in kilodaltons which is no greater than 50 kilodaltons. It is very clear from this description that 90% or more of the actual molecular weight of the polymeric polyanionic segments is 50 kilodaltons or less. With respect to claim 2, it is indicated that 90% or more of the polyanionic segments in the polymer have actual molecular weights of 40 kilodaltons or less. It is respectfully submitted that each of claims 1 and 2 recites claim language which is definite with respect to the invention which is claimed.

In claim 3, dependent on claim 1, the polyanionic segments (which 90% or more have absolute molecular weights of 50 kilodaltons or less) are said to have an average molecular weight of between 20 and 40 kilodaltons. The term “average molecular weight” used in claim 3 is a well known term to those of ordinary skill in polymer chemistry and refers to the molecular weight of the most typical chain in a given polymeric mixture. There will always be a mixture of chain sizes in a population of polymers and molecular weights reflective of those chain sizes. The average molecular weight is the absolute molecular weight of the polymeric chain which is most frequently found in a polymeric mixture. This is a well known term used by polymer chemists to describe polymeric compositions. It is respectfully submitted that based upon standard definitions used by polymer chemists to typically describe molecular weights of polymers, the present invention as set forth in claims 1-3 is in full compliance with the requirements of 35 U.S.C. §112. second paragraph.

The Rejection of Claims 1-3 Under 35 U.S.C. §102 and/or 103

The Examiner has rejected claims 1-3 under 35 U.S.C. §102 as being anticipated by or in the alternative, under 35 U.S.C. §103(a) as being obvious over U.S. patent no. 2,923,692 to Ackerman (“Ackerman”) for the reasons which are stated in the office action on pages 5-6. Applicants respectfully traverse the Examiner’s rejection.

The present invention as set forth in claims 1-3 is directed to pre-formed hydrolytically susceptible polyanionic polymer comprising at least one hydrolytically susceptible linking moiety and at least two polyanionic polymer segments linked to the linking moiety wherein all of the

polyanionic polymer segments in the polymer are linked to the whole by the linking moiety and at least 90% of the polyanionic polymer segments in the composition have molecular weights of 50 kilodaltons or less (claim 1), 40 kilodaltons or less (claim 2) or an average molecular weight which ranges from 20 kilodaltons to 40 kilodaltons. The pre-formed hydrolytically susceptible polyanionic polymers are particularly useful as barriers for use in treating or preventing the formation of surgical adhesions, wherein the molecular weight of the polymer segments is an important feature to allow favorable characteristics including bioresorption (the ability of the body to excrete the polymer based upon its relatively small molecular weight and size). The present polymers have the claimed physicochemical characteristics, i.e., hydrolytically susceptible linking moieties and polyanionic polymeric segments which have a substantially low molecular weight consistent with its biological activity- to allow the polymers to degrade into polymeric segments which may be resorbed in vivo. Consequently, the present polymers may be used within the body to treat or prevent adhesions which occur secondary to surgery and over time, will degrade into polymeric segments which may be resorbed, i.e., removed from inside the body. Ackerman neither discloses nor even obliquely suggests the present polymers.

Ackerman discloses mucilaginous polymers which are crosslinked polyanionic polymers which are swellable in water because of the existence of a large number of carboxy moieties in the polymer. Most of the polymers in Ackerman are directed to water-stable mucilaginous polymers, not hydrolytically susceptible polymers according to the present invention. Nowhere does Ackerman suggest that the polymers may be used to treat or prevent surgical adhesions or that the molecular weight of the polyanionic polymer segments is important to the functioning of the polymer as it is in the present invention. In the case of the Examiner's rejection and in particular the disclosure in Ackerman (Example IV, Polymers C-E and J), there is no discussion whatsoever about the importance of the molecular weight of the polyanionic segments. There is absolutely no disclosure in Ackerman that the polymers of Example IV have polymeric segments which meet the limitations of the present invention or the importance of molecular weight to provide bioresorbable polymers. Ackerman cannot be taken to anticipate the present invention because there is absolutely no mention of molecular weight, the importance of molecular weight to the biological activity of the polymer or that the Ackerman polymers are susceptible to water hydrolysis such that the polyanionic segments are linked together through the hydrolytically susceptible linking moieties to form the copolymer. Indeed, the examples upon which the Examiner relies make no disclosure or attempt to control molecular weight by varying the process for producing the polymer. In contrast to the present copolymers which will hydrolyze

into individual polymeric units of relatively small molecular size which is consequential to the biological activity of the present invention, the Ackerman polymers are devoid of any teaching which would lead to the presently claimed invention. There is absolutely no evidence that any of the polymers of Ackerman meet the limitations of the present claims and consequently, Applicants respectfully submit that the Ackerman polymers do not anticipate the present invention.

Certainly the teachings of Ackerman do not render the present invention obvious. There is absolutely no motivation to produce the compositions of the present invention from the teachings of Ackerman inasmuch as Ackerman is not concerned with bioresorbability of polyanionic polymeric segments linked together through hydrolytically susceptible linker moieties. There is absolutely no attempt in the Ackerman examples to control the molecular weight of the polymer consistent with its use according to the present invention. Although Ackerman does disclose polymeric formulations which can be used in the gastrointestinal tract, etc. there is not evidence that these polymers of Ackerman are formulated to be water susceptible in a manner which will result in small polymeric polyanionic segments, an important feature of the present invention related to its biological function. There is no need for Ackerman to control for molecular weight of the disclosed polymers and there is no indication that he did so. Indeed, if anything, there is motivation in Ackerman to *increase* the molecular size of the polymers in order to avoid having the polymers be absorbed from the gastrointestinal tract. Ackerman, in this sense, represents a teaching away. This stands in marked contrast to the present invention where the molecular weight and size of the polyanionic segments is a primary feature of the present invention because it provides the presently claimed invention with the ability to be used in a patient's body at a surgical site and be resorbable from that patient's body- a characteristic which is not even considered by Ackerman and is excluded by his use of polymeric composition in the gastrointestinal tract.

It is respectfully submitted that Ackerman neither teaches nor renders obvious the present invention. The mere fact that Ackerman discloses hydrogels neither anticipates the present invention nor renders the present invention obvious. The hydrogel characteristic will be a function of the number of carboxy moieties and the relative hydrophilicity of the polymer- it has little to do with molecular weight. If anything, the polymers of Ackerman have higher molecular weight, not lower molecular weight as discussed at column 13, lines 7-11, which disclose the polymers as having high viscosities. There is absolutely nothing disclosed in Ackerman which

would motivate the routineer to produce the polymeric compositions according to the present invention because there is simply no activity or biological problem discussed or disclosed in Ackerman which would require a solution such that the present compositions would be produced. Indeed, as discussed above, there is motivation to increase molecular weight. There is accordingly no motivation in Ackerman to produce the present invention.

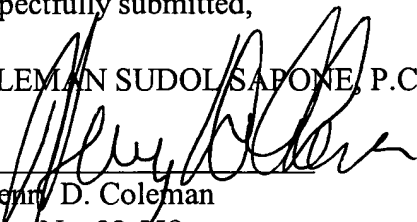
Inasmuch as there is no disclosure of the present invention in Ackerman and absolutely no motivation to produce polymeric compositions according to the present invention, it is respectfully submitted that the present invention of claims 1-3 is neither disclosed nor rendered obvious. The present invention is clearly patentable.

It is respectfully submitted that the claimed invention is in compliance with the requirements of 35 U.S.C. For the above reasons, Applicant respectfully asserts that the claims set forth in this amendment are now in condition for allowance and such action is earnestly solicited.

Applicant has cancelled 9 claims and added no claim. No fee is due for the presentation of this amendment. Small entity applies to the present application. If the Examiner determines that any fee is due for the presentation of this amendment, authorization to charge deposit account 04-0838 is hereby acknowledged. The Examiner is cordially requested to call the undersigned should the Examiner wish to expeditiously advance prosecution of this application.

Respectfully submitted,

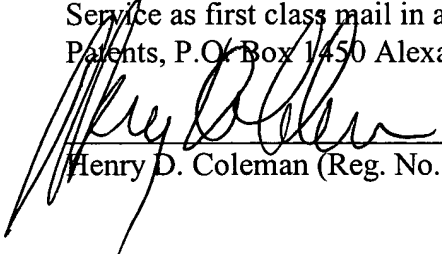
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I hereby certify that this correspondence is being deposited with the U.S. Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450 Alexandria, Virginia 22313-1450 on March 25, 2005.


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